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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,376	02/07/2001	Jian-Bing Fan	A-68929-4/DJB/RMS/DCF	7981

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EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/779,376	Applicant(s) FAN ET AL.	
	Examiner Frank W Lu	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,9-16,19-23,26 and 30-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,9-16,19-23,26 and 30-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 14 November 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10/2007</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of RCE and the amendment filed on October 5, 2007 have been entered. The claims pending in this application are claims 5, 9-16, 19-23, 26, and 30-64. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of amendment filed on October 5, 2007.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. New Matter

Claims 5, 9-16, 19-23, 26, and 30-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation "hybridizing a plurality of 96 first ligation probes to said first target domains" and "hybridizing a plurality of 96 second ligation probes to said second target domains" is added to steps a) and b) of the newly amended independent claims 5, 32, 39, and 57

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while the recitation “hybridizing a plurality of 96 first ligation probes to said first target domains” and “hybridizing a plurality of 96 second ligation probes to said second target domains” is added to steps b) and c) of the newly amended independent claims 26, 33, 54, and 58. Although the specification describes that “[G]enerally the number of individual arrays is set by the size of the microtiter plate used; thus, 96 well, 384 well and 1536 well microtiter plates utilize composite arrays comprising 96, 384 and 1536 individual arrays, although as will be appreciated by those in the art, not each microtiter well need contain an individual array. It should be noted that the composite arrays can comprise individual arrays that are identical, similar or different. That is, in some embodiments, it may be desirable to do the same 2,000 assays on 96 different samples; alternatively, doing 192,000 experiments on the same sample (i.e. the same sample in each of the 96 wells) may be desirable” (see page 41, first paragraph), page 6, line 7; page 13, lines 9-12; page 14, lines 12-13; page 15, lines 9-10; page 38, line 31 through page 39, line 15, and page 41, lines 1-10 of the specification suggested by applicant fail to define or provide any disclosure to support such claim recitation because nowhere in these parts of the specification describes hybridizing a plurality of 96 first ligation probes to said first target domains of the plurality of target sequences and hybridizing a plurality of 96 second ligation probes to said second target domain of the plurality of target sequences.

MPEP 2163.06 notes “IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981).” MPEP 2163.02 teaches that “Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject

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matter is not described in that application.” MPEP 2163.06 further notes “WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT “NEW MATTER” IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*” (emphasis added).

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5, 9-16, 19-23, 26, and 30-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 5 or 32 or 39 or 57 is rejected as vague and indefinite in view of steps g) and h). Since steps g) and f) do not indicate how contacting said amplicons with an array of capture probes is correlated with the nucleotide at each said detection position of said plurality of target sequences, it is unclear how to determine the nucleotide at each said detection position of said plurality of target sequences as recited in step h). Please clarify.

7. Claim 5 or 32 or 39 or 57 recites the limitation “each said ligation complex” in steps b), c) and e) the claim. There is insufficient antecedent basis for this limitation in the claim because the phrase “each said ligation complex” means each of said ligation complexes and there is no phrase “ligation complexes” before the phrase “each said ligation complex”. Please clarify.

8. Claim 5 or 32 or 39 or 57 recites the limitation “each said ligated probe” in step f) of the claim. There is insufficient antecedent basis for this limitation in the claim because the phrase

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“each said ligated probe” means each of said ligated probes and there is no phrase “said ligated probes” before the phrase “each said ligated probe”. Please clarify.

9. Claim 5 or 32 or 39 or 57 recites the limitation “each said detection position of said plurality of target sequences” in step h) of the claim. There is insufficient antecedent basis for this limitation in the claim because the phrase “each said detection position of said plurality of target sequences” means each of said detection positions of said plurality of target sequences and there is no phrase “said detection positions of said plurality of target sequences” before the phrase “each said detection position of said plurality of target sequences”. Please clarify.

10. Claim 26 or 33 or 54 or 58 is rejected as vague and indefinite in view of steps g) and f). Since steps g) and f) do not indicate how contacting said amplicons with an array of capture probes is correlated with the nucleotide at each said detection position of said plurality of target sequences, it is unclear how to determine the nucleotide at each said detection position of said plurality of target sequences as recited in step h). Please clarify.

11. Claim 26 or 33 or 54 or 58 recites the limitation “each said ligation complex” in steps c) and e) the claim. There is insufficient antecedent basis for this limitation in the claim because the phrase “each said ligation complex” means each of said ligation complexes and there is no phrase “ligation complexes” before the phrase “each said ligation complex”. Please clarify.

12. Claim 26 or 33 or 54 or 58 recites the limitation “each said ligated probe” in step f) of the claim. There is insufficient antecedent basis for this limitation in the claim because the phrase “each said ligated probe” means each of said ligated probes and there is no phrase “said ligated probes” before the phrase “each said ligated probe”. Please clarify.

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13. Claim 26 or 33 or 54 or 58 recites the limitation "each said detection position of said plurality of target sequences" in step h) of the claim. There is insufficient antecedent basis for this limitation in the claim because the phrase "each said detection position of said plurality of target sequences" means each of said detection positions of said plurality of target sequences and there is no phrase "said detection positions of said plurality of target sequences" before the phrase "each said detection position of said plurality of target sequences". Please clarify.

Conclusion

14. No claim is allowed.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

January 3, 2008



FRANK LU
PRIMARY EXAMINER